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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,577	12/12/2003	David M. Waisman	ME03-009	2576

7590 06/24/2005

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EXAMINER	
VIVLEMORE, TRACY ANN	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 06/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/735,577	WAISMAN, DAVID M.	
	Examiner	Art Unit	
	Tracy Vivlemore	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-44* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 2-8, 17 and 18, drawn to a composition that modulates activity of a p11 protein wherein the composition is an antisense p11 polynucleotide, classifiable in class 536, subclass 24.5. Election of this group requires further election of a single nucleotide sequence as set forth below.

II. Claims 2, 3, 9-13, 17 and 18, drawn to a composition that modulates activity of a p11 protein wherein the composition is a small interfering RNA specific to p11, classifiable in class 536, subclass 24.5. Election of this group requires further election of a single nucleotide sequence as set forth below.

III. Claims 2 and 14-18, drawn to a composition that modulates activity of a p11 protein wherein the composition is a sense p11 polynucleotide, classifiable in class 536, subclass 23.1.

IV. Claims 19-36, drawn to methods of modulating activity of p11, classifiable in class 514, subclass 44. Election of this group requires further election of a single nucleotide sequence as set forth below.

V. Claims 37-41, drawn to a method of making a clonal cell, classifiable in class 435, subclass 455. Election of this group requires election of a species as set forth below

VI. Claim 42, drawn to a clonal cell line produced by the method of claim 37, classifiable in class 435, subclass 325.

VII. Claims 43 and 44, drawn to a method of identifying a composition that modulates p11 activity, classifiable in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

1. Inventions I-III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. Invention I is an antisense p11 polynucleotide that modulates p11 activity by hybridizing to an mRNA and activating RNAse H and decreasing the amount of p11 in the cell, invention II is a small interfering RNA that modulates p11 activity by activating the RISC complex and decreasing the amount of p11 in the cell and invention III is a sense p11 polynucleotide that modulates p11 activity by increasing the amount of p11 in the cell.

2. Furthermore, examining any of inventions I-III together would impose a serious search burden. In the instant case, prior art searches of compositions of antisense polynucleotides are not coextensive with prior art searches of compositions of small interfering RNAs or sense polynucleotides. Search of each of these inventions would require different key word searches of each compound using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office

in terms of both search and examination. As such, it would be burdensome to perform examination of any of inventions I-III together.

3. Claim 1 link(s) inventions I-III. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

4. Inventions I-III are related to invention IV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product could be used in a materially different process, for example a sense polynucleotide could be used in *in vitro* hybridization assays.

5. Furthermore, examining any of inventions I-III together with invention IV would impose a serious search burden. In the instant case, prior art searches of compositions that modulate p11 activity are not coextensive with prior art searches of methods of modulating p11 activity. Search of each of these inventions would require different key word searches of each compound using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of any of inventions I-III together with invention IV.

6. Inventions I-III and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of inventions I-III is to modulate p11 activity while the function of invention V is to make a clonal cell line.

7. Furthermore, examining any of inventions I-III together with invention V would impose a serious search burden. In the instant case, prior art searches of compositions that modulate p11 activity are not coextensive with prior art searches of methods of making clonal cell lines. Search of each of these inventions would require different key word searches of each compound using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both

search and examination. As such, it would be burdensome to perform examination of any of inventions I-III together with invention V.

8. Inventions I-III and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of inventions I-III is to modulate p11 activity while invention VI is a clonal cell line.

9. Furthermore, examining any of inventions I-III together with invention VI would impose a serious search burden. In the instant case, prior art searches of compositions that modulate p11 activity are not coextensive with prior art searches of clonal cell lines. Search of each of these inventions would require different key word searches of each compound using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of any of inventions I-III together with invention VI.

10. Inventions I-III and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of inventions I-III is to modulate p11 activity while the function of invention VII is to identify compounds that modulate p11 activity.

11. Furthermore, examining any of inventions I-III together with invention VII would impose a serious search burden. In the instant case, prior art searches of compositions that modulate p11 activity are not coextensive with prior art searches of methods of identifying compounds that modulate p11 activity. Search of each of these inventions would require different key word searches of each compound using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of any of inventions I-III together with invention VII.

12. Inventions IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of invention IV is to modulate p11 activity while the function of invention V is to make a clonal cell line.

13. Furthermore, examining invention IV together with invention V would impose a serious search burden. In the instant case, prior art searches of methods of modulating p11 activity are not coextensive with prior art searches of methods of making clonal cell lines. Search of each of these inventions would require different key word searches of each compound using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and

examination. As such, it would be burdensome to perform examination of inventions IV and V together.

14. Inventions IV and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of invention IV is to modulate p11 activity while invention VI is a clonal cell line.

15. Furthermore, examining invention IV together with invention VI would impose a serious search burden. In the instant case, prior art searches of methods of modulating p11 activity are not coextensive with prior art searches of clonal cell lines. Search of each of these inventions would require different key word searches of each compound using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of invention IV together with invention VI.

16. Inventions IV and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of invention IV is to modulate p11 activity while the function of invention VII is to identify compounds that modulate p11 activity.

17. Furthermore, examining invention IV together with invention VII would impose a serious search burden. In the instant case, prior art searches of methods of modulating p11 activity are not coextensive with prior art searches of methods of identifying compounds that modulate p11 activity. Search of each of these inventions would require different key word searches of each compound using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of invention IV together with invention VII.

18. Inventions V and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product could be produced by a materially different process, for example a clonal cell could be produced without first characterizing the activity of a protein produced by the cell.

19. Furthermore, examining invention V together with invention VI would impose a serious search burden. In the instant case, prior art searches of methods of making a clonal cell line are not coextensive with prior art searches of clonal cell lines per se. Search of each of these inventions would require different key word searches of each compound using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art

literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of invention V together with invention VI.

20. Inventions V and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of invention V is to make a clonal cell line while the function of invention VII is to identify compounds that modulate p11 activity.

21. Furthermore, examining invention V together with invention VII would impose a serious search burden. In the instant case, prior art searches of methods of making clonal cell lines are not coextensive with prior art searches of methods of identifying compounds that modulate p11 activity. Search of each of these inventions would require different key word searches of each compound using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of invention V together with invention VII.

22. Inventions VI and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product (MPEP § 806.05(h)). In the instant case the process could be practiced with a materially different product, for example, screening for modulators of a protein can be performed in a cell-free environment.

23. Furthermore, examining any of inventions VI and VII together would impose a serious search burden. In the instant case, prior art searches of compositions that modulate p11 activity are not coextensive with prior art searches of methods of modulating p11 activity. Search of each of these inventions would require different key word searches of each compound using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of inventions VI and VII together.

Restriction to a single nucleotide sequence

Claims 5-7, 10-13, 20, 24, 29 and 34 are subject to an additional restriction since they are not considered to be a proper genus/Markush. See MPEP 803.02 - PRACTICE RE MARKUSH-TYPE CLAIMS - If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction. Since the decisions in In re

Weber, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and In re Haas, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. In re Harnish, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1)share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Claims 5-7, 10-13, 20, 24, 29 and 34 specifically claim multiple SEQ ID NOS, which are targeted to and modulate the expression of p11. Although the nucleotide sequences claimed each target and modulate expression of p11, the instant sequences are considered to be unrelated, since each sequence claimed is structurally and functionally independent and distinct for the following reasons: each sequence has a unique nucleotide sequence and each sequence targets a different and specific region of p11. As such the Markush/genus of sequences in claims 5-7, 10-13, 20, 24, 29 and 34 are not considered to constitute a proper genus, and are therefore subject to restriction. Furthermore, a search of more than one (1) of the sequences claimed in claims 5-7, 10-13, 20, 24, 29 and 34 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search in terms of computer time needed to perform the search and the subsequent analysis of the search results by the examiner. In view of the foregoing, one (1) sequence is considered to be a reasonable number of sequences for examination. Accordingly, if any of groups I, II or IV is elected,

applicants are required to further elect one (1) sequence from claims 5-7, 10-13, 20, 24, 29 and 34. Note that this is not a species election.

Species Election

This application contains claims directed to the following patentably distinct species of the claimed invention: the proteins recited in claim 38.

If group V is elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 37 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the

case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re

Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tracy Vivlemore whose telephone number is 571-272-2914. The examiner can normally be reached on Mon-Fri 8:45-5:15.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now

contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see http://pair-direct.uspto.gov.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Tracy Vivlemore
Examiner
Art Unit 1635

TV
June 10, 2005

JAMES SCHULTZ
PATENT EXAMINER